EXHIBIT D

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

DIANNE M. BELLEW,

Plaintiff,

v. CIVIL ACTION NO. 2:13-cv-22473

ETHICON, INC., et al.,

Defendants.

MEMORANDUM OPINION AND ORDER
(*Daubert* Motions)

The following motions have been brought by the defendants, Ethicon, Inc. and Johnson & Johnson (collectively, "the defendants"): (1) Motion to Exclude or, Alternatively, to Limit the Opinions and Testimony of Dr. Howard Jordi, Ph.D. [Docket 118]; (2) Motion to Exclude the Opinions and Testimony of Prof. Dr. –Ing. Thomas Mühl [Docket 107]; (3) Motion to Limit the Testimony of Prof. Dr. Med. Uwe Klinge [Docket 101]; (4) Motion to Exclude Certain Opinions of Daniel S. Elliott, M.D. [Docket 116]; and (5) Motion to Exclude the Testimony of Dr. Vladimir Iakovlev, M.D. [Docket 121].

The following motions have been brought by the plaintiff, Dianne M. Bellew: (1) Motion to Preclude the Testimony of Defense Expert David J. Weber, M.D., M.P.H. [Docket 114]; (2) Motion to Preclude the Testimony of Defense Expert Denise M. Elser, M.D. on the Adequacy of Defendants' Warnings and Pre-Existing Myalgia [Docket 127]; (3) Motion to Preclude the Testimony of Defense Expert Christina Pramudji, M.D. on Particular Issues; and (4) Motion to Preclude Testimony of Defense Expert Stanley J. Robboy, M.D., F.C.A.P. [Docket 131].

For the reasons explained below, the defendants' motion with respect to Dr. Jordi [Docket 118] is **DENIED as moot in part** and **DENIED in part**. The defendants' motion with respect to Dr. Mühl [Docket 107] is **DENIED**. The defendants' motion with respect to Dr. Klinge [Docket 101] is **DENIED as moot**, **DENIED in part**, and **GRANTED in part**. The defendants' motion with respect to Dr. Elliott [Docket 116] is **GRANTED in part**, **DENIED as moot in part**, **DENIED in part** and **RESERVED in part**. The defendants' motion with respect to Dr. Iakovlev [Docket 121] is **DENIED as moot in part**, **GRANTED in part**, and **DENIED in part**.

The plaintiff's motion with respect to Dr. Weber [Docket 114] is **DENIED**. The plaintiff's motion with respect to Dr. Elser [Docket 127] is **GRANTED**. The plaintiff's motion with respect to Dr. Pramudji [Docket 129] is **GRANTED in part** and **DENIED in part**. The plaintiff's motion with respect to Dr. Robboy [Docket 131] is **DENIED**.

I. Background

This bellwether case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 67,000 cases currently pending, approximately 22,000 of which are in the Ethicon, Inc. MDL, MDL 2327. In this particular case, the plaintiff was surgically implanted with the Prolift Anterior Pelvic Floor Repair System ("Prolift"), a mesh product manufactured by Ethicon and Johnson & Johnson (collectively, "Ethicon") to treat POP. (*See* Short Form Compl. [Docket 1], at 2).[1] The plaintiff received her surgery in Arizona. (*Id.* at 3). The plaintiff claims that as a result of implantation of the Prolift, she has experienced multiple complications, including mesh

[1] I have selected this case as a Prolift bellwether case in the Ethicon MDL. (*See* Pretrial Order # 98 [Docket 29], at 1).

erosion, mesh contraction, inflammation, dyspareunia (pain during sexual intercourse), urinary incontinence, chronic pain, and recurring prolapse of organs. (Master Compl. ¶ 49). In addition, she had four additional operations to remove and revise the mesh. (Pl. Fact Sheet [Docket 206-1], at 7). The plaintiff alleges negligence, failure to warn, design defect, common law fraud, fraudulent concealment, negligent misrepresentation, breach of express warranty, violation of consumer protection laws, gross negligence, and punitive damages. (Short Form Compl. [Docket 1], at 4; *see also* Pl.'s Opp. to Defs.' Mot. for Summ. J. [Docket 153], at 1 n.1 (stating that the plaintiff will not pursue several of the claims set forth in her short form complaint)). The parties have retained experts to render opinions regarding the elements of these causes of action, and the instant motions involve the parties' efforts to exclude or limit the experts' opinions and testimony pursuant to *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993).

II. Legal Standard

Under Federal Rule of Evidence 702, expert testimony is admissible if the expert is "qualified . . . by knowledge, skill, experience, training, or education," and if his testimony is (1) helpful to the trier of fact in understanding the evidence or determining a fact in issue; (2) "based upon sufficient facts or data"; and (3) "the product of reliable principles and methods" that (4) have been reliably applied "to the facts of the case." Fed. R. Evid. 702. The U.S. Supreme Court established a two-part test to govern the admissibility of expert testimony under Rule 702—the evidence is admitted if it "rests on a reliable foundation and is relevant." *Daubert*, 509 U.S. at 597. The proponent of expert testimony does not have the burden to "prove" anything to the court. *Md. Cas. Co. v. Therm-O-Disk, Inc.*, 137 F.3d 780, 783 (4th Cir. 1998). He or she must, however, "come forward with evidence from which the court can determine that the proffered testimony is properly admissible." *Id.*

The district court is the gatekeeper.[2] It is an important role: "[E]xpert witnesses have the potential to be both powerful and quite misleading[;]" the court must "ensure that any and all scientific testimony . . . is not only relevant, but reliable." *Cooper v. Smith & Nephew, Inc.*, 259 F.3d 194, 199 (4th Cir. 2001) (citing *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999) and *Daubert*, 509 U.S. at 588, 595). In carrying out this role, I "need not determine that the proffered expert testimony is irrefutable or certainly correct"—"[a]s with all other admissible evidence, expert testimony is subject to testing by 'vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof.'" *United States v. Moreland*, 437 F.3d 424, 431 (4th Cir. 2006) (quoting *Daubert*, 509 U.S. at 596); *see also Md. Cas. Co.*, 137 F.3d at 783 (noting that "[a]ll *Daubert* demands is that the trial judge make a 'preliminary assessment' of whether the proffered testimony is both reliable . . . and helpful").

Daubert mentions specific factors to guide the court in making the overall reliability determinations that apply to expert evidence. These factors include (1) whether the particular scientific theory "can be (and has been) tested"; (2) whether the theory "has been subjected to peer review and publication"; (3) the "known or potential rate of error"; (4) the "existence and maintenance of standards controlling the technique's operation"; and (5) whether the technique has achieved "general acceptance" in the relevant scientific or expert community. *United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003) (quoting *Daubert*, 509 U.S. at 593–94).

Despite these factors, "[t]he inquiry to be undertaken by the district court is 'a flexible one' focusing on the 'principles and methodology' employed by the expert, not on the conclusions reached." *Westberry*, 178 F.3d at 261 (quoting *Daubert*, 509 U.S. at 594–95); *see*

[2] With more than 67,000 cases related to surgical mesh products currently pending before me, this gatekeeper role takes on extraordinary significance. Each of my evidentiary determinations carries substantial weight with the remaining surgical mesh cases. Regardless, while I am cognizant of the subsequent implications of my rulings in these cases, I am limited to the record and the arguments of counsel.

also Kumho Tire Co. v. Carmichael, 526 U.S. 137, 150 (1999) ("We agree with the Solicitor General that '[t]he factors identified in *Daubert* may or may not be pertinent in assessing reliability, depending on the nature of the issue, the expert's particular expertise, and the subject of his testimony.'") (citation omitted); *see also Crisp*, 324 F.3d at 266 (noting "that testing of reliability should be flexible and that *Daubert*'s five factors neither necessarily nor exclusively apply to every expert").

With respect to relevancy, *Daubert* further explains:

> Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful. The consideration has been aptly described by Judge Becker as one of fit. Fit is not always obvious, and scientific validity for one purpose is not necessarily scientific validity for other, unrelated purposes. . . . Rule 702's helpfulness standard requires a valid scientific connection to the pertinent inquiry as a precondition to admissibility.

Daubert, 509 U.S. at 591–92 (internal citations and quotation marks omitted).

Finally, in several of the instant *Daubert* motions, a specific scientific methodology comes into play, dealing with differential diagnoses or etiologies. "Differential diagnosis, or differential etiology, is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. The Fourth Circuit has stated that:

> A reliable differential diagnosis typically, though not invariably, is performed after "physical examinations, the taking of medical histories, and the review of clinical tests, including laboratory tests," and generally is accomplished by determining the possible causes for the patient's symptoms and then eliminating each of these potential causes until reaching one that cannot be ruled out or determining which of those that cannot be excluded is the most likely.

Id. A reliable differential diagnosis passes scrutiny under *Daubert*. An unreliable differential diagnosis is another matter:

> A differential diagnosis that fails to take serious account of other potential causes may be so lacking that it cannot provide a reliable basis for an opinion on

> causation. However, "[a] medical expert's causation conclusion should not be excluded because he or she has failed to rule out every possible alternative cause of a plaintiff's illness." The alternative causes suggested by a defendant "affect the weight that the jury should give the expert's testimony and not the admissibility of that testimony," unless the expert can offer "no explanation for why she has concluded [an alternative cause offered by the opposing party] was not the sole cause."

Id. at 265–66 (internal citations omitted).

Ultimately, the district court has broad discretion in determining whether to admit or exclude expert testimony, and the "the trial judge must have considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Cooper*, 259 F.3d at 200 (quoting *Kumho Tire*, 526 U.S. at 152).

Before I review these motions, I begin by addressing three arguments that apply to many of the parties' *Daubert* objections. First, as I have maintained throughout these MDLs, I will not permit the parties to use experts to usurp the jury's fact-finding function by allowing an expert to testify as to a party's state of mind or on whether a party acted reasonably. *See, e.g.*, *Huskey v. Ethicon, Inc.*, 2:12-cv-05201, 2014 WL 3362264, at *3 (S.D. W. Va. July 8, 2014); *Lewis, et al. v. Ethicon, Inc.*, 2:12-cv-4301, 2014 WL 186872, at *6, *21 (S.D. W. Va. Jan. 15, 2014); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 611, 629 (S.D. W. Va. 2013). Although an expert may testify about his or her review of internal corporate documents solely for the purpose of explaining the basis for his or her opinions—assuming the opinions are otherwise admissible—a party's knowledge, state of mind, or other matters related to corporate conduct and ethics are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury.

Second, "opinion testimony that states a legal standard or draws a legal conclusion by applying law to the facts is generally inadmissible." *United States v. McIver*, 470 F.3d 550, 562

(4th Cir. 2006). I have diligently applied this rule to previous expert testimony, and I continue to adhere to it in this case. I will not parse the expert reports and depositions of each expert in relation to these same objections. I trust that able counsel in this matter will tailor expert testimony at trial accordingly.

Last, with respect to the arguments that certain experts' testimony is litigation driven, I note that an expert's formulation of his or her opinion for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert v. Merrell Dow Pharm., Inc.* ("*Daubert II*"), 43 F.3d 1311, 1317 (9th Cir. 1995) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-cv-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). In sum, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable. But I will consider the independence of an expert's testimony as evidence that his "research comports with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Having addressed these universal objections, I now turn to the defendants' *Daubert* motions.

III. The Defendants' *Daubert* Motions

In this case, the defendants seek to limit or exclude the expert opinions of Dr. Howard Jordi, Dr. Thomas Mühl, Dr. Uwe Klinge, Dr. Daniel S. Elliott, and Dr. Vladimir Iakovlev.

A. Motion to Exclude or, Alternatively, to Limit the Opinions & Testimony of Dr. Howard Jordi, Ph.D.

The defendants seek to exclude or limit the expert opinions of Dr. Howard Jordi, Ph.D. Dr. Jordi is a biochemist who founded Jordi Labs, which "provide[s] high quality analytical services to the polymer and plastics industry." (Jordi Report [Docket 135], at 1). He also served as president and CEO of Jordi Labs from 1980 to 2008. (*Id.*). The plaintiff offers Dr. Jordi to testify that (1) polypropylene degrades; (2) as a result of the chemical and physical degradation that occurs while in the body, the Prolift mesh fibers become brittle and crack; and (3) Ms. Bellew's explanted Prolift mesh degraded and cracked while in her body. (Pl.'s Resp. in Opp. to Defs.' Mot. & Mem. of Law to Exclude or, Alternatively, to Limit the Ops. & Test. of Dr. Howard Jordi, Ph.D. ("Pl.'s Resp. re: Jordi") [Docket 157], at 2). The defendants contend that Dr. Jordi should be prohibited from testifying about degradation entirely, but that in the alternative, the court should exclude his opinions regarding: (1) any clinical or mechanical effects of degradation; (2) degradation beyond the surface of the Prolene fibers; (3) mesh explants taken from patients other than the plaintiffs; (4) environmental stress cracking; (5) his belief that PVDF is a viable alternative design; and (6) Ethicon's knowledge, intentions, or beliefs with respect to PVDF. (Mem. of Law in Supp. of Defs.' Mot. to Exclude or, Alternatively, to Limit the Ops. & Test. of Dr. Howard Jordi, Ph.D. ("Defs.' Mem. re: Jordi") [Docket 119], at 2). For the reasons discussed below, the defendants' motion with respect to Dr. Jordi is **DENIED as moot in part** and **DENIED in part**.

1. Degradation Generally

Throughout their *Daubert* briefing, the defendants contend that expert opinions on degradation are not helpful to the jury because the plaintiff cannot prove specific causation and because no expert can say that degradation is clinically significant. As I have previously held in these MDLs, general causation opinions are helpful to the jury and fit the facts of this case

regardless of whether the plaintiff may ultimately fail to carry her burden to show that she was harmed by the Prolift implant. Accordingly, I reject the defendants' argument with regard to the relevancy of degradation in the context of all expert witnesses.

2. Qualifications

Next, the defendants contend that Dr. Jordi is unqualified to opine on the clinical or mechanical effects of degradation. (Defs.' Mem. re: Jordi [Docket 119], at 7). The plaintiff concedes that "Dr. Jordi will not offer medical opinions[.]" (Pl.'s Resp. re: Jordi [Docket 157], at 3). Therefore, the defendants' motion with regard to the clinical effects of degradation is **DENIED as moot**.

The defendants also contend that Dr. Jordi is unqualified to opine on the mechanical effects of degradation because he is "not a mesh design specialist or biomechanical engineer." (Defs.' Mem. re: Jordi [Docket 119], at 7). Dr. Jordi has an undergraduate degree in Chemistry and a Ph.D. in biochemistry. (Jordi Report [Docket 135] at 1). He is the founder of Jordi Labs, which specializes in the analysis of polymers, like polypropylene. (*Id.*). In his expert report, Dr. Jordi states that he has been analyzing polypropylene for over 25 years. (*Id.*). Furthermore, in *Lewis*, the court allowed Dr. Jordi to offer expert opinions about polypropylene degradation without objection. (*See* Lewis Trial Tr. [Docket 157-1], at 19). Accordingly, I **FIND** that Dr. Jordi is qualified to opine on the mechanical effects of degradation.

The defendants also appear to make a reliability argument regarding Dr. Jordi's degradation opinions. However, in his expert report, Dr. Jordi describes numerous tests he performed on Ms. Bellew's mesh explant, and subsequently concludes that based on his review of the scientific literature and his knowledge, training, and experience in polymer science, "this level of degradation will have a *strong impact* on fiber mechanical properties." (Jordi Report [Docket 135], at 22). Accordingly, I **FIND** Dr. Jordi's opinions regarding the mechanical effects

of degradation sufficiently reliable under *Daubert*.

3. Non-party Explants

Next, the defendants argue that the court should exclude any opinions or evidence concerning explants removed from non-parties. (Defs.' Mem. re: Jordi [Docket 119], at 9). The plaintiff concedes that "Dr. Jordi will not offer . . . opinions concerning his review of other explants." (Pl.'s Resp. re: Jordi [Docket 157], at 3). Therefore, the defendants' motion with regard to non-party explants is **DENIED as moot**.

4. Surface Degradation

Next, the defendants contend that if Dr. Jordi is permitted to opine on the degradation of Ms. Bellew's mesh, these opinions should be limited to surface degradation, given that Dr. Jordi has not observed any degradation of the inner layer of Ms. Bellew's mesh. (Defs.' Mem. re: Jordi [Docket 119], at 10). As discussed more fully above, Dr. Jordi is qualified to opine on degradation, and his opinions are reliable. Nowhere in his expert report does Dr. Jordi specifically opine that the "inner layer" of Ms. Bellew's mesh degraded. If the defendants are concerned that the jury will incorrectly infer that Dr. Jordi's use of the term "degradation" generally includes the inner layer of Ms. Bellew's mesh, they are free to clarify that issue at trial. Accordingly, the defendants' motion with regard to surface degradation is **DENIED**.

5. Environmental Stress Cracking

Next, the defendants argue that Dr. Jordi's opinions on environmental stress cracking ("ESC") are unreliable, unhelpful, and inadmissible. (Defs.' Mem. re: Jordi [Docket 119], at 11). The defendants claim that Dr. Jordi is unable to offer an opinion on ESC to a reasonable degree of scientific certainty. I disagree. The defendants attempt to conflate Dr. Jordi's opinion that Ms. Bellew's Prolene mesh was *susceptible* to ESC with the opinion that the mesh actually underwent ESC. Dr. Jordi specifically states that he cannot definitively determine whether

oxidation or ESC caused the cracking. (*See* Jordi Dep. [Docket 118-3], at 96-97). However, in both his expert report and deposition, he opines, to a reasonable degree of scientific certainty, that Ms. Bellew's mesh was *susceptible* to ESC. (Jordi Report [Docket 135], at 166; Jordi Dep. [Docket 118-3], at 98). Dr. Jordi's opinion is based on his examination of Ms. Bellew's mesh and supported by peer-reviewed literature. Accordingly, the defendant's motion with regard to ESC is **DENIED**.

6. PVDF as Alternative Polymer

Next, the defendants contend that Dr. Jordi's opinions regarding PVDF as an alternative polymer are unreliable because he fails to cite any peer-reviewed studies establishing that PVDF is safer and more effective than Prolene. The defendants' emphasis on safety and efficacy relates back to their original argument regarding the relevancy of degradation, which I rejected above. Disregarding this argument, the defendants are incorrect in their assertion that Dr. Jordi fails to cite any peer-reviewed studies in support of his opinion. In his expert report, when discussing PVDF, Dr. Jordi cites the Celine Mary study and Ethicon's dog study. (*See* Jordi Report [Docket 135], at 7, 9). Furthermore, I previously allowed Dr. Jordi to testify that "PVDF is much more resistant to degradation than polypropylene, and that polypropylene is more susceptible to degradation." (Lewis Trial Tr. [Docket 157-1], at 41). Accordingly, the defendants' motion with regard to PVDF is **DENIED**.

7. Ethicon's Knowledge, Intentions, Beliefs

Lastly, the defendants ask the court to exclude Dr. Jordi's opinions about Ethicon's knowledge, intentions, or beliefs regarding PVDF. (Defs.' Mem. re: Jordi [Docket 119], at 14). The plaintiff concedes that "Dr. Jordi will not offer opinions concerning Ethicon's state of mind or corporate conduct." (Pl.'s Resp. re: Jordi [Docket 157], at 14). Therefore, the defendants' motion with regard to Ethicon's knowledge, intentions, and beliefs is **DENIED as moot**.

B. Motion to Exclude the Opinions & Testimony of Dr. Thomas Mühl

The defendants seek to exclude the opinions and testimony of Dr. –Ing. Thomas Mühl. Dr. Mühl holds a Ph.D. in electrical engineering and, along with Dr. Uwe Klinge, developed a concept called "effective porosity," which is defined as a percentage of the area of mesh that has a pore size of greater than one millimeter in all directions. (Mühl Report [Docket 107-1], at 2). The effective porosity threshold is based on the theory that pores should be at least one millimeter in all directions in order to (1) prevent fibrotic bridging and (2) permit tissue ingrowth. (*See id.*). Utilizing his effective porosity theory, Dr. Mühl determined that Ethicon's Prolift has an effective porosity of 26.0%. (*Id.* at 26).

I have previously reviewed the reliability of Dr. Mühl's effective porosity theory under *Daubert*. *See Lewis, et al. v. Ethicon, Inc., et al.*, No. 2:12-cv-4301, 2014 WL 186872, at *3-5 (S.D. W. Va. Jan. 15, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Lewis* still govern. Furthermore, to the extent that there are differences in fact and exhibits, the court does not find them sufficiently material. In *Lewis*, I ruled as follows:

> First, Ethicon argues that Dr. Mühl's opinions are not reliable because they are not generally accepted. The concept of effective porosity is apparently adopted only in articles authored by Drs. Mühl and Klinge, and it is used only by a single manufacturer, FEG Textiltechnik ("FEG"), a company affiliated with Drs. Mühl and Klinge. But general acceptance is merely one factor a court should consider in determining admissibility of expert testimony. A court should consider numerous factors, none of which is dispositive, in determining whether an expert's methods pass muster under *Daubert*. *See United States v. Crisp*, 324 F.3d 261, 266 (4th Cir. 2003). In addition to general acceptance, a court should consider whether an expert's theories have been "subjected to peer review and publication." *Daubert*, 509 U.S. at 593. Dr. Mühl's effective porosity theories are published in several peer-reviewed articles. (*See, e.g.*, Mühl Dep. [Docket 161-6], at 244:14-245:19; Klinge Report [Docket 132-1], at 18 (citing Mühl T. et al., *New Objective Measurement to Characterize the Porosity of Textile Implants*, J. Biomed. Mater. Res. Part B: Applied Biomaterials 176-183 (2007)), *id.* (citing J. Otto et al., *Elongation of Textile Pelvic Floor Implants Under Load is Related to Complete*

Loss of Effective Porosity, thereby Favoring Incorporation of Scar Plates, J. Biomed. Mater. Res. Part A 1-6 (2013))).

Second, Ethicon argues that these opinions are unreliable because Drs. Mühl and Klinge have contradicted themselves in the past by stating that pores measuring less than one millimeter can be effective. (*See* Defs.' Mem. re: Mühl [Docket 138], at 8). An expert's contradictory prior statements may indicate that the expert's methods are unreliable, but that is not necessarily dispositive. The relevant inquiry is whether the proffered opinions are sufficiently reliable under *Daubert*. Dr. Klinge explained in his deposition that they adopted the one millimeter parameters in reliance on the Conze study and his research with Dr. Bernd Klosterhalfen. (*See* Klinge Dep. [Docket 161-10], at 376:14-377:16; 663:13-664:3). With support from a peer-reviewed publication, I am not convinced that opinions regarding the one millimeter parameters are unreliable.

Third, Ethicon suggests that the methods for testing effective porosity are unreliable because they were developed for FEG, a direct competitor of Ethicon. But as Ethicon admits, "a proffered expert witness's financial interest often goes to the weight rather than the admissibility of testimony." (Defs.' Mem. re: Mühl [Docket 138], at 7). "[I]t is well-settled that an expert witness's bias goes to the weight, not the admissibility of the testimony, and should be brought out on cross-examination." *Grant Thornton, LLP v. F.D.I.C.*, 297 F. Supp. 2d 880, 884 (S.D.W. Va. 2004) (Faber, J.). Ethicon is free to highlight this conflict of interest on cross-examination.

Fourth, Ethicon contends that even if I permit Dr. Mühl to testify about his effective porosity opinions, I should still prohibit his opinions regarding "effective porosity under strain" because they fail to take into account the wide range of physical forces exerted on implanted mesh. (*See* Defs.' Mem. re: Mühl [Docket 138], at 9-11). In order to test the TVT mesh's effective porosity while subjected to the mechanical forces of the human body, Dr. Mühl applied uniaxial forces (pulling from one side) between a range of 102 grams and 1,000 grams to the mesh. Ethicon argues that, in the human body, meshes are subject to forces from multiple directions simultaneously and that the actual forces to which urethral slings are subjected are estimated to be less than 50 grams. (*See* Defs.' Mem. re: Mühl [Docket 138], at 10). The plaintiffs retort that Ethicon used the same uniaxial loads to test its own products. (*See, e.g.*, Mühl Report [Docket 137-1], at 6 ("Ethicon's manner of applying uniaxial loads to Ethicon mesh to determine the behavior of mesh is strikingly similar to our test method.")). Further, Dr. Klinge explained that because slings are only one centimeter wide, any force attempting to make a sling wider will be very small (*see* Klinge Dep. [Docket 161-10], at 483:7-9), and the downward forces exerted on the sling by the pelvic floor will create a largely uniaxial strain (*id.* at 482:22-438:5). Finally, Dr. Mühl's expert report cites a published study employing similar uniaxial tensile testing methods to analyze Ethicon slings. (*See* Mühl Report [Docket 137-1], at 6).

> Lastly, Ethicon argues that Dr. Mühl impermissibly relied on unreliable medical opinions of Dr. Klinge, but Ethicon does not point to any specific statements or opinions that it challenges. (*See* Defs.' Mem. re: Mühl [Docket 138], at 11). In any event, I address Ethicon's challenges to Dr. Klinge below.
>
> Ethicon's arguments do not convince me that Dr. Mühl's opinions regarding effective porosity are unreliable. I therefore **FIND** that Dr. Mühl's opinions regarding effective porosity are not excluded.

Lewis, 2014 WL 186872, at *3-5. Therefore, I **ADOPT** my prior ruling on Dr. Mühl, as stated in *Lewis*, and **FIND** that his opinions regarding effective porosity are sufficiently reliable under *Daubert*.

C. Motion to Limit the Testimony of Dr. Uwe Klinge

The defendants seek to limit the opinions of Dr. Uwe Klinge. Dr. Klinge is a former hernia surgeon with extensive research experience in the area of biomaterials and surgical mesh. The plaintiff offers Dr. Klinge to opine on the biomaterials used in Ethicon's Prolift and how certain design deficiencies have resulted in numerous complications. Ethicon moves to preclude "Dr. Klinge from offering opinions at trial related to the following topics: (1) Ethicon's alleged knowledge, bad acts, state of mind, and corporate conduct; (2) mesh degradation, fraying, and particle loss, (3) effective porosity; and (4) alternative design." (Defs.' Mot. to Limit the Test. of Prof. Dr. Med. Uwe Klinge [Docket 101], at 1). For the reasons discussed below, the defendants' motion is **DENIED as moot**, **DENIED in part**, and **GRANTED in part**.

1. State of Mind

First, the defendants argue that Dr. Klinge's "narrative summary of Ethicon documents and Depositions and his opinions concerning Ethicon's knowledge, state of mind, and corporate conduct should be excluded." (Defs.' Mem. in Supp. of Mot. to Limit. The Test. of Prof. Dr. Med. Uwe Klinge ("Defs.' Mem. re: Klinge") [Docket 102], at 2). However, the plaintiff "has no intention of eliciting testimony from Dr. Klinge that would characterize Ethicon's state of mind

or corporate intent." (Pl.'s Resp. in Opp. to Defs.' Mot. to Limit the Test. of Prof. Dr. Med. Uwe Klinge ("Pl.'s Resp. re: Klinge") [Docket 149], at 5). Therefore, the defendants' motion with regard to Ethicon's state of mind is **DENIED as moot**.

2. Mesh Degradation, Fraying, & Particle Loss

Next, the defendants contend that "the [c]ourt should further exclude Dr. Klinge's general opinion that the Prolift is defective because its mesh degrades in vivo and is subject to fraying and particle loss" because he cannot explain the clinical significance of these alleged conditions. (Defs.' Mem. re: Klinge [Docket 102], at 3). I disagree. In his expert report, Dr. Klinge ascribes particular complications to degradation, fraying, and particle loss. For instance, when discussing degradation, he states "that oxidation of mesh . . . . leads to embrittlement of the material, impaired tissue mobility and eventually chronic pain." (Klinge Report [Docket 101-2], at 18). In his discussion of fraying and particle loss, Dr. Klinge also states that "particulates scattered throughout the pelvic tissue will create an inflammatory response of some magnitude; will increase the overall foreign body reaction and inflammatory response; will increase the amount of the fibrotic reaction; and will run the risk of migrating into other parts of the body." (*Id.* at 21). Furthermore, throughout both of these sections of his expert report, Dr. Klinge supports his opinions, at least in part, by citing to peer-reviewed, published literature. (*See* Klinge Report [Docket 101-2], at 18-21 (citing studies by Costello, Clave, and Moalli, to name a few)). Therefore, consistent with my decision in *Lewis*, I **FIND** that Dr. Klinge is permitted to testify generally about polypropylene's tendency to degrade, fray, or lose particles and its effect on the human body. *See* 2014 WL 186872, at *7.

3. Effective Porosity

Next, the defendants argue that "the court should exclude Dr. Klinge's opinions regarding effective porosity" by "incorporate[ing] by reference their motion to exclude Dr. Mühl and the

memorandum supporting the same." (Defs.' Mem. re: Klinge [Docket 102], at 6). Dr. Klinge's opinions regarding effective porosity are based on Dr. Mühl's testing, examined above. (*See* Klinge Report [Docket 101-2], at 15-16 ("In connection with this litigation, Prof. Mühl performed testing on Ethicon's surgical mesh product [Prolift/TVT Products] using the same protocol as we used in our study in 2007 and as reported again in 2013.")). Therefore, for the reasons discussed in relation to Dr. Mühl, and consistent with my decision in *Lewis*, I **FIND** that Dr. Klinge is permitted to testify about effective porosity and pore deformation. *See* 2014 WL 186872, at *7.

4. Alternative Design

Lastly, the defendants contend that "Dr. Klinge should be precluded from testifying about feasible alternative designs" because his expert report does not explain the basis for his opinion that PVDF is a safer design. (Defs.' Mem. re: Klinge [Docket 101], at 6). The plaintiff argues that I previously allowed Dr. Klinge to opine on alternative design in *Lewis* and that he references the same publications in his *Bellew* report that he referenced in his *Lewis* report. The plaintiff is mistaken. In *Lewis*, Dr. Klinge cited multiple peer-reviewed studies to support his opinions on Dynamesh, including the Klink and Silva studies. *See* 2014 WL 186872, at *7. Here, Dr. Klinge simply states that "[t]he PVDF product is a safer design for all of the reasons stated above," referencing his discussion of effective porosity. (Klinge Report [Docket 101-1], at 16). In the section of his report specifically addressing alternative design, Dr. Klinge fails to cite *any* peer-reviewed studies. (*See id.* at 24-27). Dr. Klinge's report provides no indication that his alternative design opinions are based on anything other than his and Dr. Mühl's effective porosity testing and internal Ethicon documents, which are not sufficiently reliable scientific bases under *Daubert*. (*See* Defs.' Reply in Supp. of Mot. to Limit the Test. of Prof. Dr. Med. Uwe Klinge [Docket 162], at 3-4 ("Nowhere does Dr. Klinge report that this [effective porosity]

testing was conducted on a mesh made of PVDF, nor does Dr. Klinge state elsewhere in his report that PVDF mesh would perform differently under similar testing.")). Accordingly, I **FIND** that Dr. Klinge's alternative design opinions should be **EXCLUDED**.

D. Motion to Exclude Certain Opinions of Daniel S. Elliott, M.D.

The defendants seek to exclude certain opinions of Dr. Daniel S. Elliott. Dr. Elliott is an associate professor of urology, section of Female Urology and Reconstructive Surgery, at Mayo Clinic Graduate School of Medicine in Rochester, Minnesota who has treated hundreds of patients with mesh-related complications. (Elliott Report [Docket 116-1], at 2). In preparation for this litigation, Dr. Elliott consulted approximately 300 publications, reviewed Ms. Bellew's medical records, and performed an independent medical examination of Ms. Bellew. (Pl.'s Resp. to Defs.' Mot. to Exclude Certain Ops. Of Daniel S. Elliott, M.D. ("Pl.'s Resp. re: Elliott") [Docket 150], at 2). In his expert report, Dr. Elliott concludes that (1) the Prolift has a lack of clinical benefit; (2) the Prolift causes serious and potentially permanent injuries due to complications associated with its implantation; (3) Ethicon failed to completely disclose to physicians and patients the risks of using the Prolift; and (4) Ethicon breached its duty of reasonable care. (*See* Elliott Report [Docket 116-1], at 3-5). The defendants move to exclude the following opinions offered by Dr. Elliott: (1) the defendants' knowledge, state of mind and alleged bad acts; (2) legal opinions; (3) product marketing; (4) regulatory opinions; (5) matters that do not fit the facts of this case; (6) supposed underreporting of complications; (7) other matters for which Dr. Elliott lacks support; (8) degradation; (9) patents; (10); physician training; (11) communications between Plaintiff and her treating physicians; (12) Ethicon's discontinuation of the Prolift; (1) and opinions not set forth in his report. (Defs.' Mot. to Exclude Certain Ops. of Daniel S. Elliott, M.D. [Docket 116], at 1). I agree with the plaintiff that the

defendants have taken a "scatter-shot" approach, which would be better suited for a motion *in limine*. (Pl.'s Resp. re: Elliott [Docket 150], at 1). Nevertheless, I proceed to review each objection in turn.

1. State of Mind

The defendants point out various instances where Dr. Elliott opines on Ethicon's knowledge or state of mind. (*See* Defs.' Mem. re: Elliott [Docket 117], at 2-3). The plaintiff appears to agree that Dr. Elliott may not opine on Ethicon's alleged knowledge or state of mind, but argues that Dr. Elliott's statements regarding what Ethicon did or did not do "go beyond opinions about Ethicon's state of mind or corporate conduct." (Pl.'s Resp. re: Elliott [Docket 150], at 5 (internal quotation marks omitted)). I disagree. Whether Ethicon studied certain issues, provided information, or provided guidance are all examples of corporate conduct. (*See* Elliott Report [Docket 116-1] at 42, 44). As I previously discussed, Ethicon's state of mind, knowledge, or corporate conduct are not appropriate subjects of expert testimony because they are not helpful to the jury. *See* Fed. R. Evid. 702. Therefore, these opinions are **EXCLUDED.**

2. Legal Opinions

The defendants argue that Dr. Elliott should be precluded from testifying as to what a "reasonably prudent medical device manufacturer would or would not do." (Defs.' Mem. re: Elliott [Docket 117], at 3). The plaintiff "agrees that Dr. Elliott will not use the phrases 'reasonably prudent medical device manufacturer' or 'duty of reasonable care.'" Therefore, the defendants' motion with regard to legal opinions is **DENIED as moot.**

3. Marketing Opinions

The defendants contend that Dr. Elliott is unqualified to offer opinions on Ethicon's marketing of the Prolift. (*Id.* at 4). The plaintiff concedes that Dr. Elliott is not an expert in

marketing and "true marketing opinions should be excluded." Nevertheless, I agree with the plaintiff that Dr. Elliott's statement that "the Prolift System should have never been marketed to surgeons or patients in the first place," addresses the Prolift's safety, and not the defendants' marketing techniques. (Elliott Report [Docket 116-1], at 3). Therefore, the defendants' motion with regard to marketing opinions is **DENIED as moot in part** and **DENIED in part**. To the extent that the defendants have further objections, they are free to raise them at trial.

4. Regulatory Opinions

The defendants ask this court to preclude Dr. Elliott from providing regulatory opinions because he has conceded that he is not a regulatory expert. (Defs.' Mem. re: Elliott [Docket 117], at 5). The plaintiff indicates that she "does not intend to raise any FDA clearance issues" (Pl.'s Resp. re: Elliott [Docket 150], at 6). Therefore, the defendants' motion with regard to regulatory opinions is **DENIED as moot.**

5. Irrelevant Opinions

a. Alleged Complications the Plaintiff Never Developed, Including Mesh Erosion & Performance of a Cystoscopy

First, the defendants argue that Dr. Elliott's opinions on conditions the plaintiff never suffered should be excluded because they are irrelevant, including "adhesions, vaginal retraction and shortening, fistula formation, chronic infection, chronic wound healing issues, organ erosion, bladder perforation, rectal perforation, vascular injury, injury to the pudendal nerve, nerve entrapment, chronic inflammatory process, and [ ]sarcomas." (Def.'s Mem. re: Elliott [Docket 117], at 6 (internal quotation marks omitted)). The defendants also ask the court to exclude Dr. Elliott's opinions on mesh erosion—because the plaintiff's mesh did not erode—and cystoscopies—because the plaintiff did not require or receive one. (*Id.* at 7). The plaintiff claims that all ways in which a product might injure a particular plaintiff are relevant under Arizona

law; and furthermore, the plaintiff did in fact suffer some of the complications the defendants wish to exclude. (Pl.'s Resp. re: Elliott [Docket 150], at 8-9).

Evidence of complications that the plaintiff did not experience is irrelevant and lacking in probative value. First, in regard to the plaintiff's strict liability claim, I disagree with the plaintiff's reading of *Golonka v. General Motors Corp.*, 65 P.3d 956 (Ariz. 2003). The plaintiff asserts that "likelihood of injury," one of the factors assessed under the risk/benefit analysis, refers to the likelihood of *any* injury. However, a strict liability claim requires "the defective condition proximately cause *the plaintiff's* injury[.]" *Anderson v. Nissei ASB Mach. Co.*, 3 P.3d 1088, 1092 (Ariz. 1999) (emphasis added). Reading the elements of the prima facie case and the risk/benefit factors together, the pertinent injury is clearly that which the plaintiff actually suffered. Second, although the plaintiff's argument that *any* warning is relevant to proximate cause based on Dr. Dehasse's testimony has some merit, elaborating on injuries that the plaintiff did not incur risks "confusing the issues [and] misleading the jury." Fed. R. Evid. 403. Therefore, the defendants' motion on this issue is **GRANTED** and Dr. Elliott's opinions on complications the plaintiff never developed are **EXCLUDED**. To the extent that the parties disagree as to what complications the plaintiff suffered, these objections are better suited for trial.

b. Mesh Procedures Not Administered to the Plaintiff

Next, the defendants contend that Dr. Elliott's opinions about mesh procedures that the plaintiff did not undergo do not fit the facts of the case. (Defs.' Mem. re: Elliott [Docket 117], at 8). The plaintiff "agrees that Dr. Elliott will not address the posterior and apical Prolift procedures." (Pl.'s Resp. re: Elliott [Docket 150], at 7). Therefore, the defendants' motion with regard to mesh procedures not administered to the plaintiff is **DENIED as moot.**

c. Prolift Appropriateness for Certain Populations

Lastly, the defendants argue that Dr. Elliott's opinions on Ethicon's marketing of the Prolift to overweight and elderly patients are irrelevant, given that the plaintiff is neither overweight nor elderly. (Defs.' Mem. re: Elliott [Docket 117], at 8). Again, the plaintiff "agrees that Dr. Elliott will not talk about whether the Prolift is appropriate for overweight and elderly patients." (Pl.'s Resp. re: Elliott [Docket 150], at 7 (internal quotation marks omitted)). Therefore, the defendants' motion with regard to the Prolift's appropriateness for certain populations is **DENIED as moot.**

6. Underreporting of Complications

The defendants argue that Dr. Elliott's opinions on the underreporting of complications should be excluded because they are conclusory and unreliable. (Defs.' Mem. re: Elliott [Docket 117], at 8). Dr. Elliott only cites one peer-reviewed article that the defendants argue examines drugs, not medical devices. (*Id.* at 9). However, the plaintiff points out that although the Kessler article focuses on drugs, the author also discusses "device-induced disease." (Pl.'s Resp. re: Elliott [Docket 150], at 11). Dr. Elliott's decision to rely on the Kessler article indicates his opinions are not conclusory and that he utilized a reliable methodology. Whether the defendants disagree with Dr. Elliott's ultimate conclusion that the Kessler article supports his opinion with regard to medical devices is not a sufficient basis to object under *Daubert*. Additionally, the defendants' concern with the lack of additional support goes to the weight of Dr. Elliott's testimony and can be adequately addressed on cross-examination. Accordingly, the defendants' motion with regard to underreporting of complications is **DENIED.**

7. Other Matters Lacking Support

In its seventh point, the defendants list ten page references where Dr. Elliott allegedly

fails to support his opinions with "citations to medical literature or other information." (Defs.' Mem. re: Elliott [Docket 117], at 9-10). The defendants provide no further explanation as to why these portions of Dr. Elliott's report should be excluded under *Daubert*. Without more specific information, I am unable to review the merits of such a motion. One instance with which the defendants take specific issue is Dr. Elliott's opinion on anatomic recurrence rates. Although Dr. Elliott fails to cite any scientific literature in his discussion of this topic in his report, when asked about anatomic recurrence rates during his deposition, Dr. Elliott indicates he relied on three different papers in coming to this conclusion. (Elliott Dep. [Docket 116-2], at 113 (naming Chmielewski, Walters, and Weber)). Dr. Elliott's response is sufficient to establish reliability under *Daubert*. Therefore, the defendants' motion with regard to anatomic recurrence rates is **DENIED.**

8. Degradation

The defendants argue that Dr. Elliott is unqualified to opine on mesh degradation and that his opinions are "unconnected to any reliable methodology." (Defs.' Mem. re: Elliott [Docket 117], at 11-15). With regard to his qualifications, the defendants contend that Dr. Elliott has no experience in the field of polymer science and has not shown that he possesses any specialized knowledge observing mesh degradation in his practice. (*Id.* at 13).

An expert may be qualified by "knowledge, skill, experience, training, or education." Fed. R. Evid. 702. "One knowledgeable about a particular subject need not be precisely informed about all the details of the issues raised in order to offer an [expert] opinion." *Thomas J. Kline, Inc. v. Lorillard, Inc.*, 878 F.2d 791, 799 (4th Cir. 1989). Dr. Elliott has personally treated patients with Prolift mesh complications "too numerous to count." (Elliott Dep. [Docket 116-2], at 178). He has published nearly 60 peer-reviewed articles and given over 100 lectures pertaining

to POP. (Elliott Report [Docket 116-1], at 2). Additionally, he has published two scientific manuscripts dealing specifically with polypropylene mesh. (*Id.*). According to Dr. Elliott, his "practice has become increasingly dedicated to treating a whole host of life-altering complications associated with the use of both SUI and POP meshes, including meshes made by Ethicon." (*Id.*). Therefore, I **FIND** that Dr. Elliott is qualified to offer opinions on mesh degradation.

With regard to his methodology, Dr. Elliott bases his opinions on both his clinical experience, as well as his extensive review of the scientific literature and internal Ethicon documents. Specifically, in the section of his report discussing mesh degradation, Dr. Elliott cites numerous peer-reviewed studies and articles to support his assertions. (*See* Elliott Report [Docket 116-1], at 34-35 (citing Costello and Clave in the text, to name a few)). Accordingly, I **FIND** that Dr. Elliott may testify regarding mesh degradation.

9. Patents

The defendants ask the court to preclude Dr. Elliott from expressing opinions about Ethicon's patents because he is not a patent expert. (Defs.' Mem. re: Elliott [Docket 117], at 14). The plaintiff indicates that Dr. Elliott has not and will not offer expert opinions on Ethicon's patents. Therefore, the defendants' motion with regard to patents is **DENIED as moot.**

10. Physician Training

The defendants seek to preclude Dr. Elliott from testifying about physician training because his opinions are unreliable and not helpful to the jury. (*Id.* at 15). However, in their Memorandum in Support, the defendants only take issue with one particular statement by Dr. Elliott: "Ethicon representatives pushed the envelope on training." (*Id.* (quoting Elliott Report [Docket 116-1], at 43-44)). As indicated in the footnotes, the phrase "pushed the envelope" is

taken directly from an email written by an Ethicon district manager. (*See* Elliott Report [Docket 116-1], at n.285). Furthermore, although the section as a whole consists of a review of corporate documents, Dr. Elliott comments on the quality of training by pointing out where Ethicon failed to inform physicians of certain risks and complications, as well as why such information is critical. (*See, e.g.*, Elliott Report [Docket 116-1], at 48 ("Mesh exposure and bladder injury are common[ ]complications, yet there is inadequate guidance in the Surgical Guide on managing these complications. An absence of a description and guidance in the management of these complications minimizes the frequency and magnitude of these complications to a surgeon.")). In Arizona, under the risk/benefit analysis, one of the factors to be considered is "the avoidability of injury by care in use of the product (including the effect of instructions or warnings)[.]" *Golonka*, 65 P.3d at 962 n.2. I agree with the plaintiff that "[t]his standard places into issue whether Ethicon provided sufficient guidance to surgeons through the Prolift [IFU], the Surgical Guide, and any training programs offered." Accordingly, the defendants' motion with regard to physician training is **DENIED**.

11. Communications Between the Plaintiff and Her Treating Physicians

The defendants argue that Dr. Elliott's summary of the discussion between the plaintiff and her treating physician, Dr. Dehasse, should be excluded because "Dr. Elliott has no specialized knowledge enabling him to render *expert opinions* about what Dr. Dehasse did or did not discuss with Plaintiff." (Defs.' Mem. re: Elliott [Docket 117], at 15 (emphasis added)). The defendants' contention is misplaced, however, because Dr. Elliott is not offering an expert opinion in this section of his report. He is merely summarizing the factual record, which does not require the use of "scientific, technical, or other specialized knowledge." Fed. R. Evid. 702. Therefore, I will not address the admissibility of this testimony here and **RESERVE** ruling for

trial.

12. Withdrawal of Prolift

The defendants contend that Dr. Elliott's discussion of Ethicon's decision to withdraw the Prolift from the market is irrelevant because it took place after the plaintiff's implant procedure, and that Dr. Elliott is not qualified to render an opinion on Ethicon's decision. I agree with the plaintiff that "[u]ltimately, the issue of whether Defendants' withdrawal of [the] Prolift from the market is relevant to this case should be decided based on [future] briefing." (Pl.'s Resp. re: Elliott [Docket 150], at 17). Regardless, as discussed more fully above, Ethicon's state of mind—its reasoning behind the decision to withdraw the Prolift—is not an appropriate subject for expert testimony. Accordingly, the defendants' motion on this issue is **GRANTED** and Dr. Elliott's opinions on why Ethicon withdrew the Prolift are **EXCLUDED**.

13. Opinions Not Set Forth in Expert Report

Finally, the defendants seek to exclude opinions not set forth in Dr. Elliott's report as required by Federal Rule of Civil Procedure 26(a)(2)(B)(i). (Defs.' Mem. re: Elliott [Docket 117], at 16). The plaintiff concedes that there was no discussion of ischemia in Dr. Elliott's report, and that he will not opine on that subject at trial. (Pl.'s Resp. re: Elliott [Docket 150], at 17). Therefore, the defendants' motion with regard to ischemia is **DENIED as moot**. Objections to the following opinions remain: (1) granulation; (2) nerve injury; and (3) future surgeries.

a. Granulation

In his expert report, Dr. Elliott states that Dr. Dehasse and Dr. Joseph noted that Ms. Bellew experienced tissue granulation, in addition to a variety of other complications. (*See* Elliott Report [Docket 116-1], at 60-61). Dr. Elliott subsequently concludes "[t]o a reasonable degree of medical certainty, *each of* the permanent complications, injuries, and the consequences

thereof, as documented herein and in the medical records, was caused by all of the defects and problems with the Prolift discussed throughout this report." (*Id.* at 64 (emphasis added)). This conclusion clearly includes granulation, which was discussed with regard to Ms. Bellew's medical records. Accordingly, the defendants' motion with regard to granulation is **DENIED**.

b. Nerve Injury

Throughout his expert report, Dr. Elliott discusses nerve injury as "a critically important . . . condition following Prolift POP repair." (Elliott Report [Docket 116-1], at 27). However, with regard to his examination and diagnosis of Ms. Bellew, Dr. Elliott fails to specifically mention nerve injury. In his deposition, Dr. Elliott states that Ms. Bellew "possibly" had nerve injury based on his discussion of her pelvic muscle spasms in his report. Under Rule 26, expert reports must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Fed. R. Civ. P. 26(a)(2)(B)(i). Accordingly, the defendants' motion with regard to nerve injury is **GRANTED**, and Dr. Elliott's opinions on this issue are **EXCLUDED**.

c. Future Surgeries

Finally, Dr. Elliott clearly states that Ms. Bellew "will continue to . . . need future medical care," which could include future surgeries. Dr. Elliott indicates that he holds this opinion to a reasonable degree of medical certainty based on his review of Ms. Bellew's medical records, his examination of Ms. Bellew, and his knowledge and opinions on the Prolift as discussed throughout his report. Accordingly, I **FIND** that Dr. Elliott addressed future surgeries in his expert report, and that his opinions are sufficiently reliable under *Daubert*.

E. Motion to Exclude the Testimony of Dr. Vladimir Iakovlev, M.D.

The defendants seek to exclude the opinions of Dr. Vladimir Iakovlev in their entirety. Dr. Iakovlev is an anatomical pathologist and director of Cytopathology at the Department of

Laboratory Medicine at St. Michael's Hospital in Toronto, Canada. (Iakovlev Report [Docket 121-1], at 1). In his expert report, Dr. Iakovlev describes a study he participated in with Dr. Robert Bendavid beginning in 2012 to "analyze explanted meshes and . . . provide a correlation between pathological findings and clinical symptoms." (*Id.*). Based on this study, as well as his background in pathology, Dr. Iakovlev concludes "that women implanted with pelvic mesh devices are at an increased risk of suffering chronic and debilitating pelvic pain and dyspareunia as a result of the higher innervation of that anatomical region of the body compared to the anterior abdominal wall." (*Id.* at 2).

The defendants make the following arguments regarding the admissibility of Dr. Iakovlev's opinions under *Daubert*: (1) Dr. Iakovlev's opinions regarding potential complications are unreliable and irrelevant; (2) Dr. Iakovlev is unqualified to opine on degradation and his opinions are unreliable and irrelevant; (3) Dr. Iakovlev's nerve density analysis is unreliable; (4) Dr. Iakovlev's opinions regarding mesh deformation and folding are unreliable and speculative; (5) Dr. Iakovlev's opinions regarding Ms. Bellew's urinary symptoms are speculative; (6) Dr. Iakovlev's proposed testimony significantly exceeds his expertise; and (7) Dr. Iakovlev's opinion about Ms. Bellew's post-explant condition is speculative. (Defs.' Mem. of Law in Supp. of Mot. to Exclude the Ops. & Test. of Dr. Vladimir Iakovlev (Defs.' Mem. re: Iakovlev [Docket 122]). The plaintiff "agrees not to question Dr. Iakovlev on the mesh design and mesh knitting, about the other 130 surgical mesh explants he has analyzed prior to this case, the Bark Thickness Correlation Chart that uses data from other explants, or Ms. Bellew's future pain as a result of the Prolift implant." (Pl.'s Resp. in Opp. to Defs.' Mot. & Mem. of Law to Exclude the Ops. & Test. of Vladimir Iakovlev, M.D. ("Pl.'s Resp. re: Iakovlev [Docket 156], at 2). Accordingly, to the extent that the defendants' motion

relates to one of the areas of testimony conceded by the plaintiff, it is **DENIED as moot**.

1. Degradation

First, the defendants contend that the court should exclude Dr. Iakovlev's opinions regarding degradation because Dr. Iakovlev is unqualified to testify as to the chemical composition of Ms. Bellew's explanted mesh and his opinions are unreliable. (Defs.' Mem. re: Iakovlev [Docket 122], at 5-13). I have previously reviewed Dr. Iakovlev's qualifications and the reliability of his degradation opinions under *Daubert*. *See Eghnayem, et al. v. Boston Scientific Corp.*, No. 2:13-cv-07965, 2014 WL 5461991, at *46 (S.D. W. Va. Oct. 27, 2014). While the parties in this case have not relied on precisely the same arguments, my reasoning and conclusions from *Eghnayem* still govern. In *Eghnayem*, I ruled as follows:

> **a. Qualifications**
>
> A pathologist is a clinician who provides diagnoses for patient care based on the examination of specimens they receive and relevant clinical information. *Edwards*, 2014 WL 3361923, at *24 (citation omitted). In his expert report, Dr. Iakovlev states that his "professional activities include diagnostic examination of specimens surgically removed from human patients" where his "annual practice volume amounts to 5000 cases." (Iakovlev Report [Docket 105-1], at 2). Dr. Iakovlev describes himself as an "academic physician" who "pursue[s] research endeavors and teach[es] medical students and residents." (*Id.*). BSC does not question Dr. Iakovlev's pathology credentials; rather, it only argues that as a pathologist, he is unqualified to render these opinions. However, throughout these MDLs, I have allowed numerous pathologists to testify regarding the properties of polypropylene mesh. *See, e.g., Sanchez, et al. v. Boston Scientific Corp.*, No. 2:12-cv-05762, 2014 WL 4851989, at *19–20 (S.D. W. Va. Sept. 29, 2014) (discussing Dr. Richard W. Trepeta); *In re C. R. Bard, Inc.*, 948 F. Supp. 2d 589, 621 (S.D. W. Va. 2013) (discussing Dr. Bernd Klosterhalfen). In fact, in *Edwards*, I determined that Dr. Iakovlev was qualified to render opinions specific to that plaintiff's mesh based on his experience as a pathologist. *See Edwards*, 2014 WL 3361923, at *24–25. Therefore, I **FIND** that Dr. Iakovlev is qualified to offer specific causation opinions regarding Ms. Eghnayem based on his pathological examination of her mesh explants.

Eghnayem, 2014 WL 5461991, at *46. Therefore, I **ADOPT** my prior ruling on Dr. Iakovlev's qualifications, as stated in *Eghnayem*, and **FIND** that he is qualified to opine on the degradation

of Ms. Bellew's mesh in particular.

b. Reliability

In *Edwards*, I determined that "the process Dr. Iakovlev used to analyze the explant is the industry standard in pathology" and that "[m]ere disagreement among experts is not, in itself, a reason to exclude an expert's testimony." *Edwards*, 2014 WL 3361923, at *25. Therefore, I **ADOPT** my prior ruling on the reliability of Dr. Iakovlev's degradation opinions, as stated in *Edwards*, and **FIND** that he is permitted to opine on the degradation *of Ms. Bellew's mesh*.[3]

2. Nerve Density & Mesh Deformation

In his expert report, when discussing Ms. Bellew's nerve density and mesh deformation, Dr. Iakovlev compares Ms. Bellew's specimen to the transvaginal meshes in his "sample pool." (Iakovlev Report [Docket 121-1], at 93). Because the plaintiff has agreed not to ask Dr. Iakovlev about the other 130 mesh explants he reviewed prior to this case, the defendants' motion with regard to nerve density and mesh deformation is **DENIED as moot** to the extent that Dr. Iakovlev's opinions are based on his "sample pool."

3. Urinary Symptoms

In his expert report, Dr. Iakovlev opines "to a reasonable degree of medical certainty, that the mesh caused the appearance of new urinary symptoms experienced by Ms. Bellew." (Iakovlev Report [Docket 121-2], at 93). The defendants argue that this opinion is unreliable speculation because there are no allegations that Ms. Bellew's mesh was "overtightened." (Defs.' Mem. re: Iakovlev [Docket 122], at 15). Dr. Iakovlev writes that "[t]he specimen shows that the mesh was in contact with muscle bundles consistent with detrusor muscle" and that "[i]t affected nerves and neural ganglia in the area of bladder and urethral innervation." (Iakovlev Report

[3] I also permitted Dr. Iakovlev to opine on mesh degradation with regard to Ms. Eghnayem's mesh based on his "morphological differential diagnosis." *Eghnayem*, 2014 WL 5461991, at *46.

[Docket 121-2], at 93). Because Dr. Iakovlev is able to explain the basis for his opinion that the mesh caused new urinary symptoms, I **FIND** that his opinion contains sufficient indicia of reliability. Accordingly, the defendants' motion with regard to urinary symptoms is **DENIED**. To the extent that the defendants disagree with Dr. Iakovlev's ultimate conclusion, they are free to address that issue on cross-examination.

4. Proposed Testimony

Lastly, the defendants contend that Dr. Iakovlev's proposed testimony significantly exceeds his expertise. (Defs.' Mem. re: Iakovlev [Docket 122], at 15). As discussed more fully above, as a pathologist, Dr. Iakovlev is qualified to opine on the condition of Ms. Bellew's mesh. Therefore, the defendants' motion on this issue is **DENIED**.

IV. The Plaintiff's *Daubert* Motions

The plaintiff moves to limit or exclude the expert opinions of David J. Weber, M.D., M.P.H., Denise M. Elser, M.D., Christina Pramudji, M.D., and Stanley J. Robboy, M.D., F.C.A.P.

A. Motion to Preclude Testimony of Defense Expert David J. Weber, M.D., M.P.H.

The plaintiff seeks to exclude the opinions of Dr. David J. Weber. Dr. Weber is a full professor in the Department of Epidemiology, University of North Carolina Gillings School of Global Public Health with both a medical degree and master's degree in public health. (Weber Report [Docket 114-1], at 3). The defendants requested Dr. Weber to review and comment on scientific and medical literature addressing the use of the Prolift in the surgical treatment of female POP. (*Id.* at 5). In his expert report, Dr. Weber concludes that "[o]verall, the scientific literature demonstrates the Prolift is an efficacious and safe treatment for POP." (*Id.* at 7). The plaintiff argues that Dr. Weber "arbitrarily narrowed the substantial literature on the Prolift and the Gynemesh PS (the mesh material in the Prolift) to a select few articles, based upon no

recognized scientific method or process, excluding the vast majority of relevant literature from his analysis." (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude Test. of David J. Weber., M.P.H. ("Pl.'s Mem. re: Weber") [Docket 115], at 1). The plaintiff takes particular issue with Dr. Weber's decision to define "long-term" as greater than three or more years and his failure to review the Velemir article. (*See id.* at 1, 3).

I find the plaintiff's arguments wholly unconvincing. There is nothing "arbitrary" about Dr. Weber's process. Dr. Weber chose specific search and exclusion criteria based on his years of experience as an epidemiologist and reviewed only literature matching that chosen criteria. (*See* Weber Report [Docket 114-1], at 12-13 ("A PubMed (US National Library of Medicine, National Institutes of Health) search was conducted with MeSH terms 'surgical mesh' and 'pelvic organ prolapse.' All randomized controlled trials since 2005 conducted in humans and published in English were reviewed. All studies that used Prolift or Gynemesh PS in the transvaginal repair of POP in one arm were selected."); *see also id.* at 13 ("A PubMed (US National Library of Medicine, National Institutes of Health) search was conducted with MeSH terms 'surgical mesh' and 'pelvic organ prolapse' and 'follow-up studies[.]' All studies since 2005 conducted in humans and published in English were reviewed. Exclusion criteria included the following: non-epidemiologic study design[;] case series, registries, reviews, editorials; non-Prolift or Gynemesh PS products; less than 3 years follow-up duration; non-vaginal surgery (e.g. abdominal surgery) and, studies with an arm with multiple mesh products.")). Throughout his report and deposition, Dr. Weber explains why he chose the objective criteria he did. (*See e.g.*, *id.* at 7 ("The randomized, blinded (or masked) comparative clinical trial is considered the best design to study a medical intervention (treatment)."); *see also* Weber Dep. [Docket 148-1], at 92 ("The reports were selected solely on the study design and studying of Gynemesh.")).

Furthermore, Dr. Weber did not "decide" to exclude certain literature. (Pl.'s Reply in Further Supp. of *Daubert* Mot. to Preclude Ops. of David J. Weber, M.D., M.P.H. [Docket 163], at 3). Instead, he reviewed the articles that fit the criteria of his search, nothing more, nothing less. If the plaintiff is concerned that certain studies were omitted from Dr. Weber's review, she is free to address that issue on cross-examination. Accordingly, the plaintiff's motion with regard to the reliability of Dr. Weber's expert opinions is **DENIED**.

B. Motion to Preclude the Testimony of Defense Expert Denise M. Elser, M.D. on the Adequacy of Defendants' Warnings and Pre-Existing Myalgia

The plaintiff seeks to preclude the testimony of Dr. Denise M. Elser on the adequacy of the defendants' warnings and pre-existing myalgia. (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude the Test. of Denise M. Elser, M.D. on the Adequacy of Defs.' Warnings & Pre-Existing Myalgia ("Pl.'s Mem. re: Elser [Docket 128]). Dr. Elser is board-certified in female pelvic medicine and reconstructive surgery and the Medical Director of Women's Health Institute of Illinois. (Elser Report [Docket 145-1], at 1). The plaintiff argues that Dr. Elser's opinions on the adequacy of the Prolift IFU are unreliable *ipse dixit* opinions and that her opinion that the plaintiff suffered from pelvic floor myalgia before she was implanted with the Prolift is pure speculation. (Pl.'s Mem. re: Elser [Docket 128], at 7, 10). Based on slightly different reasoning than the plaintiff provides, I agree that Dr. Elser's opinions on these two issues should be **EXCLUDED** under *Daubert*.

1. Adequacy of Defendants' Warnings

The plaintiff argues that Dr. Elser's opinions on the adequacy of the Prolift IFU are unreliable because she is unfamiliar with the pertinent regulatory standards and bases her opinions solely on her status and knowledge as a surgeon. (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude the Test. of Denise M. Elser, M.D. on the Adequacy of Defs.'

Warnings & Pre-Existing Myalgia ("Pl.'s Mem. re: Elser") [Docket 128], at 7). In her reply, the plaintiff specifically indicates that she is not objecting to Dr. Elser's qualifications to opine on the adequacy of warnings. (Pl.'s Reply in Further Supp. of *Daubert* Mot. to Preclude Ops. of Denise Elser, M.D. [Docket 160], at 2). However, I have previously determined "that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks [s]he has observed in [her] own practice." *Tyree, et al. v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at *70 (S.D. W. Va. Oct. 17, 2014). The plaintiff's arguments speak to Dr. Elser's qualifications, rather than the reliability of her opinions. Dr. Elser's familiarity with IFUs comes solely from her clinical experience. (*See* Elser Dep. [Docket 127-1], at 37 (Q: [Y]ou're just basing that on your own opinions based on your own experience and what you think is reasonable. Is that fair? A: That's fair.")). In fact, she admits that she did not even know that there were regulations governing what information must be provided in the IFU. (*Id.* at 38). Dr. Elser's understanding of the possible risks associated with pelvic surgery is not sufficient to qualify her to make the broad assertion that *all* possible risks were adequately warned of in the Prolift IFU. Accordingly, consistent with my decision in *Tyree*, I **FIND** that Dr. Elser is not qualified to offer opinions on the adequacy of the Prolift IFU.

2. Pre-Existing Myalgia

The plaintiff contends that Dr. Elser's opinion that Ms. Bellew suffered from pelvic floor myalgia prior to her Prolift implantation surgery is unreliable by Dr. Elser's own admission. (Pl.'s Mem. re: Elser [Docket 128], at 10). In her deposition, Dr. Elser concedes that there is "no objective evidence in any medical record indicating that" Ms. Bellew had pelvic floor myalgia before the Prolift surgery; therefore, her opinion is speculative. (Elser Dep. [Docket 127-1], at 208). The defendants respond by arguing that Dr. Elser discusses pelvic floor myalgia

throughout her deposition and supports her opinion with facts summarized in Ms. Bellew's medical records. (Defs.' Resp. in Opp. To Pl.'s Daubert Mot. to Preclude the Test. of Defense Expert Denise M. Elser, M.D., on the Adequacy of Defs.' Warnings and Pre-Existing Myalgia [Docket 145], at 6). However, the defendants' assertion fails to support their argument.

Throughout her deposition, Dr. Elser clearly states that she does not know whether Ms. Bellew had pre-existing myalgia because she was never tested or diagnosed. (*See id.* at 90 ("So, I don't know what was preexisting[.]"); *see also id.* at 92 ("No, the answer is we don't know. She had complaints of pelvic pain, abdominal pain; and I don't see an assessment of the pelvic muscle tone on the initial evaluation so I don't know what she had."); *see also id.* at 117 ("So, I wish it had been explored more in this patient, but I can't say for sure she has it.")). First, none of these statements by Dr. Elser constitutes an expert opinion because she clearly indicates that she does not have sufficient knowledge to determine whether Ms. Bellew had pre-existing myalgia. Second, nowhere in her expert report does Dr. Elser come to the conclusion that Ms. Bellew had pre-existing myalgia based on her medical records. Although Dr. Elser attempts to connect certain "risk factors" discussed in her report back to her opinion on pre-existing myalgia in her deposition, this connection is not supported by any scientific basis or a differential diagnosis. In her expert report, Dr. Elser's discussion of pre-existing pain is merely a recitation of Ms. Bellew's medical history. Based on my review of the record, the first time Dr. Elser opines that Ms. Bellew may have had myalgia prior to her Prolift surgery is in her deposition. Dr. Elser's opinion is not held to a reasonable degree of medical certainty and was not formed using reliable methodology. Accordingly, I **FIND** that Dr. Elser's opinion that Ms. Bellew had pre-existing myalgia should be **EXCLUDED**.

C. Motion to Preclude the Testimony of Defense Expert Christina Pramudji, M.D. on Particular Issues

The plaintiff seeks to exclude the expert opinions of Dr. Christina Pramudji on "particular issues." (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude the Test. of Dr. Christina Pramudji on Particular Issues ("Pl.'s Mem. re: Pramudji") [Docket 130]). Dr. Pramudji is a board-certified urologist, with a subspecialty board certification of Pelvic Floor Medicine and Reconstructive Surgery. (Pramudji Report [Docket 146-1], at 9). The plaintiff contends that Dr. Pramudji's opinions on (1) the adequacy of the defendants' warnings and (2) smoking are unreliable, and therefore, should be excluded. (Pl.'s Mem. re: Pramudji [Docket 130], at 1). For the reasons discussed below, the plaintiff's motion with regard to Dr. Pramudji **is GRANTED in part** and **DENIED in part**.

1. Adequacy of Warnings

The plaintiff argues that Dr. Pramudji's opinions on the adequacy of the Prolift IFU are unreliable because she is unfamiliar with the pertinent regulatory standards and bases her opinions solely on her subjective beliefs and "status" as a surgeon. (*Id.* at 7). In her reply, the plaintiff specifically indicates that she is not objecting to Dr. Pramudji's qualifications to opine on the adequacy of warnings. (Pl.'s Reply in Further Supp. of *Daubert* Mot. to Preclude Certain Ops. of Christina Pramudji, M.D. [Docket 161], at 1). However, I have previously determined "that without additional expertise in the specific area of product warnings, a doctor, such as a urologist or urogynecologist, is not qualified to opine that a product warning was adequate, merely because it included the risks [s]he has observed in [her] own practice." *Tyree*, 2014 WL 5320566, at *70. The plaintiff's arguments speak to Dr. Pramudji's qualifications, rather than the reliability of her opinions. Dr. Pramudji's familiarity with IFUs comes solely from her clinical experience. (*See* Pramudji Dep. [Docket 129-1], at 64-65 ("Q: Well, in determining whether or not the IFU for the Prolift adequately warned of the risks and complications, did you base your

opinion on your own judgment and your own evaluation based on your experience? A: Yes. Q: You did not rely on any particular standards, for example, an FDA regulation or any statement by anyone at Ethicon as to what they were supposed to communicate in those warnings correct? A: Correct.")). In fact, she admits that she is not familiar with any regulations or Ethicon standards governing the Prolift IFU. (*Id.* at 16-17). Dr. Pramudji's understanding of the possible risks associated with pelvic surgery is not sufficient to qualify her to make the broad assertion that *all* possible risks were adequately warned of in the Prolift IFU. Accordingly, consistent with my decision in *Tyree*, I **FIND** that Dr. Pramudji is not qualified to offer opinions on the adequacy of the Prolift IFU. Accordingly, the plaintiff's motion with regard to adequacy of warnings is **GRANTED**.

2. Smoking

Dr. Pramudji opines that the plaintiff's history as a chronic heavy smoker has impeded her healing and contributed to her osteopenia. (Pramudji Dep. [Docket 146-2], at 130-132, 157-158). The plaintiff argues that this opinion is unreliable speculation because Dr. Pramudji "infers causation from risk alone" and fails to perform a differential diagnosis. (Pl.'s Mem. re: Pramudji [Docket 130], at 10). However, Ms. Bellew's medical records reflect that she has struggled with healing in the past. Dr. Pramudji testified that "smoking causes microcapillary damage, so without good blood supply to the vaginal area, the healing is not going to be as robust as it would" and that "[she] know[s] that [Ms. Bellew] doesn't heal well based on her neck surgery where she didn't - - her - - the bone graft didn't take very well at all. And that was attributed to her smoking." (Pramudji Dep. [Docket 129-1], at 136-137). Furthermore, Dr. Pramudji did not perform a differential diagnosis because her opinion is that smoking is a "major contributing factor" with regard to Ms. Bellew's wound healing, not the only factor or cause. (*See id.* at 144). Because Dr. Pramudji is able to explain the basis for her medical opinion that Ms. Bellew's

smoking contributed to her issues with the Prolift, I **FIND** that her opinion contains sufficient indicia of reliability. Accordingly, the plaintiff's motion with regard to smoking is **DENIED**.

D. Motion to Preclude the Testimony of Defense Expert Stanley J. Robboy, M.D., F.C.A.P.

The plaintiff seeks to exclude the expert opinions of Dr. Stanley J. Robboy, M.D., F.C.A.P. Dr. Robboy is a gynecologic pathologist with 45 years of experience and the immediate past-president of the College of American Pathologists. (Robboy Report [Docket 131-1], at 1). Dr. Robboy's expert report discusses "what is expected to be seen following tissue injury, the histologic characteristics of the body's reaction to the implantation of Ethicon's Prolift to treat [POP], a discussion of what is seen in the mesh specimens removed from Mrs. Bellew, and whether histological support exits for Mrs. Bellew's clinical complaints." (*Id.* at 3). Based on his analysis of Ms. Bellew's explanted mesh, among other things, Dr. Robboy concludes that Ms. Bellew's tissue reaction does not explain her symptomology. (*Id.* at 8). The plaintiff argues that Dr. Robboy's expert opinions should be excluded because (1) they are litigation-driven; (2) he failed to perform a reliable differential diagnosis; and (3) he relied on improper anecdotal evidence. (Pl.'s Mem. of Law in Supp. of *Daubert* Mot. to Preclude Test. of Stanley J. Robboy, M.D., F.C.A.P. ("Pl.'s Mem. re: Robboy") [Docket 132]). For the reasons discussed below, the plaintiff's motion with regard to Dr. Robboy is **DENIED**.

1. **Litigation-Driven**

First, the plaintiff contends that Dr. Robboy's expert opinions are unreliable because they are litigation-driven. Specifically the plaintiff asserts that "before this litigation, [Dr. Elliott has] never been asked to correlate pathological findings to pain" and "has never researched mesh." (Pl.'s Mem. re: Robboy [Docket 132], at 1, 4). An expert's formulation of his opinions for the purposes of litigation does not, by itself, justify that expert's exclusion. *See Daubert*, 43 F.3d at

1317) ("That an expert testifies for money does not necessarily cast doubt on the reliability of his testimony, as few experts appear in court merely as an eleemosynary gesture."). This concern, however, does have a role in applying *Daubert*. *See Hoffman v. Monsanto Co.*, No. 2:05-CV-00418, 2007 WL 2984692, at *3 (S.D. W. Va. Oct. 11, 2007) (considering in the *Daubert* analysis "[w]hether experts are proposing to testify about matters growing naturally and directly out of research they have conducted independent of the litigation, or whether they have developed their opinions expressly for purposes of testifying" (quoting Fed. R. Evid. 702 advisory committee's note)). However, I will not exclude an expert on the sole basis that the opinion arose during litigation, so long as it is otherwise reliable.

Dr. Robboy has largely based his opinions on his professional experience with mesh pathology samples examined during his practice. (Robboy Report [Docket 131-1], at 5, 8). In addition, in his expert report, Dr. Robboy writes that he would have come to the same conclusions had he "received Mrs. Bellew's specimen as 'routine' on the usual surgical pathology bench and not as part of a legal proceeding." (*Id.* at 14). In forming his opinions, Dr. Robboy reviewed Ms. Bellew's medical records and various deposition transcripts, as well as personally examined Ms. Bellew's explanted mesh both grossly and microscopically. (*Id.* at 6). Dr. Robboy's approach in no way indicates he failed to "comport with the dictates of good science." *Daubert II*, 43 F.3d at 1317. Accordingly, the plaintiff's motion with regard to Dr. Robboy's opinions being litigation-driven is **DENIED**.

2. Methodology

Next, the plaintiff argues that Dr. Robboy employs an unreliable methodology because he fails to conduct a proper differential diagnosis in concluding that the mesh did not cause Ms. Bellew's pain. (Pl.'s Mem. re: Robboy [Docket 132], at 4). I disagree. In forming his specific

causation opinions, Dr. Robboy properly relies on his clinical experience, his review of the scientific literature, and his personal examination of Ms. Bellew's medical records and explanted mesh. (*See* Robboy Report [Docket 131-1], at 5-6, 8). This methodology is typical of pathologists, including Dr. Iakovlev, the plaintiff's pathology expert. (Iakovlev Report [Docket 121-1], at 92-94).

With regard to utilizing a differential diagnosis, a plaintiff's expert can rule out alternative causes to determine that mesh, for example, is the most likely cause of the plaintiff's pain. However, as a defendant's expert, Dr. Robboy is ruling out ways in which the mesh could cause pain to come to the conclusion that there is no pathological explanation for the plaintiff's pain. In his expert report, Dr. Robboy explains the various ways in which mesh can cause pain. (*See* Robboy Report [Docket 131-1-], at 15-19 (discussing dyspareunia, nerve entrapment, mesh exposure/erosion, and mesh degradation)). He subsequently concludes, based on his examination of Ms. Bellew's mesh, there is no evidence that her explant caused her pain. (*See e.g.*, *id.* [Docket 131-1], at 16 ("From my review of Mrs. Bellew's specimen and my review of the plaintiff's expert's photographs, it is clear that no traumatic neuroma or any other nerve abnormality that would indicate pain is present, and certainly no atypical one.")). I **FIND** this approach sufficiently reliable under *Daubert*. Accordingly, the plaintiff's motion with regard to Dr. Robboy's methodology is **DENIED**.

3. Surgical Specimens

Lastly, the plaintiff argues that "Dr. Robboy's reliance on between 10 to 50 'surgical specimens' of explanted mesh is" improper anecdotal evidence. (Pl.'s Mem. re: Robboy [Docket 132], at 5). The defendants clarify that Dr. Robboy is not attempting to opine on mesh explants outside the context of the present litigation, but instead is merely forming an opinion based on his "knowledge, skill, experience, training, [and] education" stemming from his clinical practice.

Fed. R. Evid. 702; (*see also* Defs.' Resp. in Opp. to Pl.'s *Daubert* Mot. to Preclude the Test. of Stanley J. Robboy, M.D., F.C.A.P. ("Defs.' Resp. re: Robboy") [Docket 151], at 2). In his expert report, Dr. Robboy correlates tissue reactions he has observed in his own practice with the scientific literature. (*See* Robboy Report [Docket 131-1], at 5). Subsequently, Dr. Robboy concludes that

> [b]ased on my experience with other mesh specimens where I have been the examining pathologist, and with earlier extensive experience with cardiac pacemaker electrodes in the heart as well as a 45 year experience with many other tissue types and condition, the overall tissue reaction is mild and does not explain the patient's symptomology.

(*Id.* at 8). In explaining why he thinks Ms. Bellew had a mild tissue reaction, Dr. Robboy identifies various factors "typically expected with mesh specimens." (*See id.* at 15).

The plaintiff takes issue with Dr. Robboy's reliance on his clinical experience because she has no way of "independently verifying" opinions. (Pl.'s Reply to Defendants' Resp. in Opp. to Pl.'s *Daubert* Mot. to Preclude the Test. of Stanley J. Robboy, M.D., F.C.A.P. ("Pl.'s Reply re: Robboy") [Docket 171], at 2). The plaintiff's argument has no practical merit. Numerous expert witnesses throughout the course of these MDLs have relied on their clinical experience in forming their expert opinions. Such practice can hardly be described as a "mystery." (Pl.'s Mem. re: Robboy [Docket 132], at 5). If *Daubert* required an expert witness to independently verify every single clinical experience he had over the course of his career, the court would never make it past pre-trial motions. Dr. Robboy's reference and reliance on specimens he has previously examined "demonstrates his *experience* with mesh explants and their typical presentation in his normal pathology practice." (Defs.' Resp. re: Robboy [Docket 151], at 4). Furthermore, even where I have previously excluded general causation opinions based on the reliability of the samples, "[an expert's] experience reviewing the mesh in his collection may be relevant to his

qualifications." *Edwards*, 2014 WL 3361923, at *23, n.5 (discussing Dr. Iakovlev's Bendavid study). Accordingly, the plaintiff's motion with regard to Dr. Robboy's surgical specimens is **DENIED**.

V. Effect of *Daubert* Rulings

I emphasize that my rulings *excluding* expert opinions under Rule 702 and *Daubert* are dispositive of their admissibility in these cases, but my rulings *not to exclude* expert opinions are not dispositive of their admissibility. In other words, to the extent that certain opinions might be cumulative or might confuse or mislead the jury, they may still be excluded under Rule 403 or some other evidentiary rule. I will take up these issues as they arise.

VI. Conclusion

For the reasons explained above, the defendants' motion with respect to Dr. Jordi [Docket 118] is **DENIED as moot in part** and **DENIED in part**. The defendants' motion with respect to Dr. Mühl [Docket 107] is **DENIED**. The defendants' motion with respect to Dr. Klinge [Docket 101] is **DENIED as moot**, **DENIED in part**, and **GRANTED in part**. The defendants' motion with respect to Dr. Elliott [Docket 116] is **GRANTED in part**, **DENIED as moot in part**, **DENIED in part**, and **RESERVED in part**. The defendants' motion with respect to Dr. Iakovlev [Docket 121] is **DENIED as moot in part**, **GRANTED in part**, and **DENIED in part**.

The plaintiff's motion with respect to Dr. Weber [Docket 114] is **DENIED**. The plaintiff's motion with respect to Dr. Elser [Docket 127] is **GRANTED**. The plaintiff's motion with respect to Dr. Pramudji [Docket 129] is **GRANTED in part** and **DENIED in part**. The plaintiff's motion with respect to Dr. Robboy [Docket 131] is **DENIED**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: November 20, 2014

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE